UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,602	02/22/2005	John Hadden	3115.00066	4753

48924 7590 04/23/2008

KOHN & ASSOCIATES, PLLC
30500 NORTHWESTERN HWY
STE 410
FARMINGTON HILLS, MI 48334

EXAMINER	
LEWIS, PATRICK T	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
04/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,602	HADDEN ET AL.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *June 30, 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Response Dated February 7, 2008

1. Claims 24-36 are pending. An action on the merits of claims 24-36 is contained herein below.

2. The rejection of claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over Masihi, K.N. International Journal of Antimicrobial Agents (2000), Vol. 14, pages 181-191 (Masihi) has been rendered moot in view of applicant's amendment dated February 7, 2008.

3. The rejection of claims 24-36 under 35 U.S.C. 103(a) as being unpatentable over Masihi, K.N. International Journal of Antimicrobial Agents (2000), Vol. 14, pages 181-191 (Masihi) is maintained for the reasons of record as set forth in the Office Action mailed on August 21, 2007.

Rejections of Record Set Forth in the Office Action Dated August 21, 2007

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 24-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masihi, K.N. International Journal of Antimicrobial Agents (2000), Vol. 14, pages 181-191 (Masihi).

Claims 24-26, 32-33 and 35 are drawn to a method of treating or preventing an infection by administering a composition comprising an adjuvant effective amount of a

protected IMP compound. Claims 27-28 are drawn to a composition comprising an adjuvant effective amount of a protected IMP compound. Claims 29-31, 34 and 36 are drawn to a method of affecting an immune response to an infectious agent by administering a composition comprising an adjuvant effective amount of a protected IMP compound.

Masihi teaches that the immune system can be manipulated specifically by vaccination or nonspecifically by immunomodulation (page 181-182). Immunomodulators include both immunostimulatory and immunosuppressive agents. The mode of action includes augmentation of the antiinfectious immunity by the cells of the immune system including lymphocyte subsets, macrophages, and natural killer cells. Microbial products, drugs of natural and synthetic origin, and proteins derived from the immune system represent some of the immunomodulators that are currently in use. Masihi further teaches that methyl inosine monophosphate (MIMP) is an thymomimetic immunomodulator capable of inducing the expression of T lymphocyte differentiation markers in human prothymocytes (page 184). MIMP has been shown to enhance mitogen-induced proliferation of lymphocytes, augment IgM plaque-forming cells, induce delayed type hypersensitivity and normalize an impaired response to IL-2. Depressed phytohemagglutinin responses of lymphocytes suppressed by an HIV-derived peptide, interferon-□, prostaglandin PGE2 or lymphocytes from pre-AIDS (ARC) patients could be progressively restored by MIMP. The mean day death in mice infected with Fiend leukemia virus, employed as a murine model of AIDS, could be significantly delayed by MIMP.

Masihi does not explicitly teach compositions of MIMP and an active agent; however, Masihi teaches non-antibiotic agents such as immunomodulators possessing antimicrobial activity offer a novel approach as an adjunct modality for the treatment of infectious and malignant conditions. The use of immunomodulators as adjuncts or complimentary components implicitly teaches combinations with conventional active agents such as vaccines. In regards to compositions comprising an additional adjuvant, the use of materials in combination, each of which is known to function for intended purpose, is generally held to be prima facie obvious as the idea of combining them flows logically from their having been individually taught in the prior art.

6. Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive. Applicant argues that Masihi is not describing vaccines or adjuvants. Applicant contends there was no evidence at that time that MIMP or any other protected IMP could work effectively as an adjuvant to a vaccine, and thus, one would have no reason to use MIMP as an adjuvant as described by the Office Action.

In response to applicant's argument that Masihi is not describing vaccines or adjuvants, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The instantly claimed composition comprises a protected IMP compound optionally in combination with an agent chosen from the group consisting of antiviral agents, microbial agents, vaccine

agents, and combinations thereof. As set forth supra, Masihi teaches the limitations of the instantly claimed composition.

In regards to applicant's contention that there was no evidence at that time that MIMP or any other protected IMP could work effectively as an adjuvant to a vaccine, mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art; Patent Office can require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; this burden of proof is applicable to product and process claims reasonably considered as possessing allegedly inherent characteristics. Patent and Trademark Office does not have facilities for examining and comparing applicant's claimed composition with the prior art, and thus applicants have the burden of persuasion to make some comparison between materials in order to establish unexpected properties.

Conclusion

7. Claims 24-36 are pending. Claims 24-36 are rejected. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Dr. Patrick T. Lewis/
Primary Examiner, Art Unit 1623

ptl